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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,644	01/16/2004	Jeffrey I. Auerbach	INL-083CP6C5	8755

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KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP
STATE STREET FINANCIAL CENTER
ONE LINCOLN STREET
BOSTON, MA 02111-2950

EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,644

Applicant(s)

AUERBACH, JEFFREY I.

Examiner

Kenneth R. Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/19/04;1/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and **should include that which is new in the art to which the invention pertains**. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;**
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

3. The specification is objected to because of the following informality: the continuation information must be updated to reflect all patents issued from the parent applications.

4. Claims 31-32, 41-42, 52-53, and 63-64 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims further limit a circular nucleic acid molecule which is not an actual component of the kit of the base claims. Thus, other than an "intended use", these claims do not further limit the base claims, drawn to kits comprising primers and a polymerase.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 27, 34, 37, and 43-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 24, 34, 45, and 56 are confusing because they are not complete sentences. It would appear that "wherein said primers comprise" is intended rather than "comprising". Correction is required.

B) Claims 27, 37, 48, and 59 are confusing because they further comprise an agent for circularizing a nucleic acid molecule which is already stated in the base claim to be circular. Correction is required.

C) Claims 43-64 are confusing because it cannot be determined what is encompassed by a "substantially constant temperature" in claims 43 and 54.

Clarification is required.

D) Claims 44 and 55 are further confusing because it cannot be determined what is encompassed by "substantially constant reaction conditions". Clarification is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter).

Independent claims 23, 33, 43, and 54 recite the language "plurality of single-stranded polynucleotide primers". Despite the remarks in the papers filed 12/03/04, support for this language has not been found in the specification. Further, no support has been found for the language "substantially constant temperature" in claims 43 and 54, and "substantially constant reaction conditions" in claims 44 and 55. If this rejection

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is traversed, it is requested that support be pointed to with particularity (page and line numbers).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24 and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullis et al. (US 4,683,195).

These claims are drawn to kits comprising: a plurality of single-stranded polynucleotide primers; and a polymerase. It is noted that kit claims, as a type of product claim, are examined based only upon the required kit components, regardless of any intended use of such components or the kit as a whole. Thus, all language in the claims relating to circular nucleic acids and amplification thereof is not given patentable weight as merely relating to intended use.

Mullis et al. disclose kits comprising a plurality of single-stranded polynucleotide primers, and a polymerase (see column 3, lines 34-55).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US 5,270,184) in view of Mullis et al. (US 4,683,195).

Independent claims 23, 33, 43, and 54 are drawn to a kit comprising: a plurality of single-stranded polynucleotide primers; and a polymerase. In claims 43 and 54, the polymerase also has the requirement of being capable of exponential amplification under constant temperature.

Walker et al. disclose a method comprising the use of: a plurality of single-stranded polynucleotide primers; and a polymerase having strand displacement ability and able to exponentially amplify nucleic acids at a constant temperature (see entire document, especially Fig. 1 and columns 6-13).

Walker et al. do not disclose kits.

Mullis et al., as discussed above, discloses kits comprising primers and polymerase.

One of ordinary skill in the art would have been motivated to package together the primers and polymerase of Walker et al. into a kit because such a kit would have clearly been useful in carrying out the method of Walker et al. As demonstrated by Mullis et al., the use of kits for facilitating the practice of methods was conventional in the art at the time of the invention. The limitations of the dependent claims are merely

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drawn to conventional reagents used in nucleic acid manipulation and thus clearly do not contribute to patentability of the claimed kits. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

9. Claims 23-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lizardi (US 6,124,120).

Lizardi discloses a method comprising the use of: a plurality of single-stranded polynucleotide primers; and a polymerase having strand displacement ability and able to exponentially amplify nucleic acids at a constant temperature (see entire document, especially columns 2-3, 6, 8-10, and 16). Lizardi also disclose in column 17, lines 24-26, the use of kits.

Lizardi. does not explicitly disclose the exact kits of the claims.

One of ordinary skill in the art would have been motivated to package together the primers and polymerase of Lizardi et al. into a kit because such a kit would have clearly been useful in carrying out the method of Lizardi. Although Lizardi only discloses generic kits, surely the claimed kits would have been suggested since they comprise required reagents for the method of Lizardi. The limitations of the dependent claims are merely drawn to conventional reagents used in nucleic acid manipulation and thus clearly do not contribute to patentability of the claimed kits. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

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10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 23-64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,740,745. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related as species-genus.


12. Claims 23-64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,448,017. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims and the instant claims are related as species-genus.

13. No claims are free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 8/24/06
Kenneth R Horlick
Primary Examiner
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08/24/06